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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,801	06/14/2002	Norbert Kothe	100723- 12/Beil Wolff-291	4106
7590	03/29/2004			EXAMINER
Norris McLaughlin & Marcus 220 East 42nd Street 30th Floor New York, NY 10017			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	10/030,801	Applicant(s)	KOTHE et al
Examiner	SAUNDERS	Group Art Unit	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 5 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on 11/12/03

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 1-29 is/are pending in the application.

Of the above claim(s) 27-29 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-26 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

The preliminary amendment of 1/11/02 has been entered. Claims 1-29 are pending.

Applicant's election with traverse of Group I (claims 1-26) in Paper No. whatever, filed 11/12/03 is acknowledged. The traversal is on the ground(s) that Group I - III all share the common feature of reciting serum or plasma, as the same or corresponding technical feature of each Group. This is not found persuasive because the "serum" or "plasma" recited in each Group is merely a starting material used in the method, which yields multiple products (immunoglobulin in the case of claim 27, anti thrombin III in the case of claim 28) as fractions of the "serum" or "plasma". Without question the "serum" and "plasma" sources are old and provide no common or corresponding technical feature which provides anything new in the art.

The requirement is still deemed proper and is therefore made FINAL.

The disclosure is objected to because of the following informalities: at page 4, 7<sup>th</sup> line from bottom, "Coheen" is incorrect; --Goheen--is the correct author.

Appropriate correction is required.

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. By reciting "of human or animal origin" claim 2 encompasses all possible sources of the starting material to be used in the method of the base claim.

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Claims 1, 4, 6, 12-13, 17, 19, 21, 22 and 23 are objected to under 37 CFR 1.75

(i). Each recites multiple steps, or implies that there may be multiple steps. Each distinct step must be indented.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear as to whether the “hydrophobic interaction chromatography”, and “the stepwise salt gradient” are conducted with the same piece of apparatus. Is the stepwise salt gradient used to elute fractions from the recited chromatography solid phase or from some other solid phase?

In claim 1 “the starting solution” lacks antecedent basis (AB).

In claims 2 and 8-11 “starting material” is unclear. Is this the “starting solution” of claim 1 or something that is diluted to form the “solution”?

In claim 4 “the next step” lacks clear AB in claim 1. Is this a step of the gradient elution?

In claim 5 “the high...” and “the low...” lack antecedent basis.

In claim 6, “the high...” and “buffer” lack antecedent basis (AB).

In claim 7 “the chromatography phase” lacks AB; also, “the desired high salt gradient concentration” lacks AB. Does applicant intend to recite--solid--before “phase”?

In claim 9 “the starting material” and “the preparative fractionation” lack AB.

In claim 12 “the first fraction” lacks AB.

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In claims 14-15, does applicant intend to recite--solid--before each recitation of "phase"?

In claim 16 "the high...", "buffer" and "the lowered..." lack AB. Does applicant intend dependency from claim --4--rather than "1" ?

In claims 17 and 18 "the first fraction" lacks AB.

In claims 19 and 21 "the usual..." lacks AB.

In claims 20 "the second fraction" lacks AB also "especially IgG" is indefinite.

MPEP 2173.05 (d).

Claim 22 is incomprehensible as to how the steps of base claim 1 fit into this dependent claim. The claim is also confusing as to how many steps are involved and is so full of recitations lacking antecedent basis, that the examiner can only suggest that applicant present a new independent claim, with each distinct step indented in proper order, and provide proper antecedent basis for each of the following recitations:

"the permeate" at line 5;

"the first albumin solution" at lines 5-6;

"the ammonium sulfate buffer reservoir" at line 6;

"the buffer solution 1" at line 6;

"the first high step" at line 7;

"the first fraction obtained" at line 7;

"the second immunoglobulin..." at line 8;

"the low ammonium sulfate..." at line 10;

"the 2<sup>nd</sup> step" at line 10.

In claim 23 "the chromatographic column" lacks antecedent basis (AB).

In claim 24, "each recycling cycle" and "the interaction chromatography phase" lack AB. Does applicant intend insertion of --solid--before "phase"?

In claim 26 "especially" IgG is indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goheen et al (J chromatography, 326,235, 1985) in view of Goudswaard et al (Immunochemistry, 14, 717, 1977).

Goheen et al show fractionation of human serum on a column with a solid phase/matrix for hydrophobic interaction chromatography (HIC); after addition of the starting solution, the column is eluted with a linear gradient of ammonium sulfate (AS) from 1.7 to 0.0 M. Two peaks are obtained: a first (at a higher AS concentration) that contains albumin and a second (at a lower AS concentration) which contains immunoglobulin. This is precisely what applicant does in claim 1, except that applicant uses a step gradient while Goheen et al use a linear gradient.

Since it is conventional to elute a HIC column with either a linear or a stepwise gradient (e.g. as done by Goudswaard et al), it would have been obvious to modify the method of Goheen et al by using a step gradient to isolate the two fractions taught.

When thus modified, the method of Goheen et al would be consistent with instant claims 1-4 and 7.

Regarding claims 14-15 Goheen et al teach use of a TSK-Phenyl-5pw matrix, which is consistent with claim limitations; see instant specification page 9, 2<sup>nd</sup> and 3<sup>rd</sup> full para.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Saunders/tgd

March 23, 2004

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